



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

FILE COPY

May 19, 2000

Mr. Steve Jwanouskos
Boston Scientific EP Technologies, Inc.
2710 Orchard Parkway
San Jose, CA 95134

Dear Mr. Jwanouskos:

Your petition requesting the Food and Drug Administration to grant a variance from application of the performance standard for electrode lead wires and patient cables regulation, was received by this office on 05/18/00. It was assigned docket number 00P-1304/CP 1 and it was filed on 05/19/00. Please refer to this docket number in the future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe
Dockets Management Branch

00P-1304

ACK 1